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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,941	03/11/2004	Martha G. Welch	5199-134	8041

56949 7590 05/13/2008

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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
05/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,941	WELCH ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8,17 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8,17 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 27, 2007 has been entered.

Petition Decision

Applicant's petition under 37 CFR § 1.78, filed October 27, 2008 has been DISMISSED, wherein the decision was mailed to Applicant on April 30, 2008.

Response to Amendment/Arguments

Applicant's amendments and arguments filed February 28, 2007 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Because the Petition under 37 CFR § 1.78 has been dismissed, the declaration filed on October 26, 2007 under 37 CFR 1.131 has been considered, but is ineffective to overcome the Hollander (US 2006/0105939 A1) reference. Further, it is noted that Applicant has not provided Exhibit A (the copies of the relevant laboratory notebook pages).

Additionally, the Oath is objected to as being defective as it recites continuity to a provisional application for which the priority claim was denied in the Petition Decision of April 30, 2008.

Specification

The disclosure is objected to because of the following informalities: Because Applicant's petition under 37 CFR § 1.78 has been dismissed, the amendment to the specification is inappropriate. Further, as described in the Petition Decision, amendments to the specification cannot incorporate by reference the material of any previous application.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8, 17 and 21 are/rmain rejected under 35 U.S.C. 103(a) as being unpatentable over HOLLANDER in view of NIH News Alert, both presented *supra*, and in further view of SWAIN (E. Swain. Pharmaceutical and Medical Packaging News (1999) 4 pages) and PIERCE (PIERCE Technical Resource Sheet TR0043.0 "Protein Stability and Storage" 6/03, 3 pages), for the reasons of record and those set forth below.

The instant claims are drawn to compositions of OT/S, kits thereof, for a variety of intended uses, optionally with a protease inhibitor.

Arguments pertaining to the Petition under 37 CFR § 1.78 and the benefit of priority claimed will not be addressed, as the Petition has been dismissed.

Applicant argues that because the claims recite 'synergistic', the prior art combination cannot render the combination obvious. Further, Applicant argues that the NIH alert does not discuss repeated dosages or use in children, thus Applicant asserts there is no expectation that it will synergistically treat autism.

As stated previously, *In re Kerkhoven* is applicable as it is the combination of two compounds useful for the same purpose- treating autism- which are combined to make a third composition for treating autism which would flow logically from the teachings in the art.

Applicant point to support in the specification for term 'synergistic', e.g. ¶ 75, 86 and 87, and to Figure 22 (described in ¶ 47). Respectfully, the examiner disagrees that this is evidence of synergy, as there is no comparison of both components administered separately and compared to the combination. Here, Applicant only presents one element of the combination alone, and relies upon unsupported statements that the combination is synergistic. MPEP 716.02(a) states (in part), "Evidence of a greater than expected result may also be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately (i.e., demonstrating "synergism"). *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). However, a greater than additive effect is not necessarily sufficient to overcome a *prima facie* case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte The NutraSweet Co.*, 19 USPQ2d 1586

(Bd. Pat. App. & Inter. 1991)." Here, Applicant has not met the burden of demonstrating that the effect is greater than the sum of each taken separately, and that the effect is to an unobvious extent.

Additionally, in looking to the specification for the preferred embodiments, ¶ 88 states that the secretin is administered at 1-100 mg/day and in another embodiment administered about 0.001-1000 mg/day, where the oxytocin is administered at 0.001-100 mg/day and preferably at 1-100 mg/day. The acceptable ranges that are 'preferred embodiments' span 7 orders of magnitude and embrace routine dosages administered for therapeutic purposes, and when read in light of the specification, any combination of oxytocin and secretin at dosage between 0.001 and 1000 mg/day of each component would be 'synergistic'.

Hollander teaches treating autism with oxytocin (claim 1) and that, "Agents suitable for use in combination therapy are any chemical compound or treatment method useful to patients with disorders associated with repetitive behaviors…" (paragraph [0046]).

NIH News Alert teaches treating autism with secretin (e.g. page 2, citing Horvath, et al.).

Swain teaches that packaging of pharmaceuticals can add to the 'bottom line' by reducing theft, counterfeiting, increasing shelf life, and improve patient compliance (page 1 of 4).

PIERCE teaches that protease inhibitors are added to protein solutions to lengthen shelf life (e.g. Table 2, page 2) by preventing cleavage of proteins.

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." Thus,

because both oxytocin and secretin have been taught in the prior art as useful for treating autism, it would have been obvious to have combined the two for making a composition for the same purpose.

With regards to the kit, the examiner has interpreted 'kit' broadly to include packaging for sale. It would have been obvious at the time of the invention to have packaged the pharmaceutical composition in any packaging for the benefit of reducing theft, reducing counterfeiting and increasing shelf life of the compound, as well as for the benefit of product recognition during sales of the product. One would have been motivated to have packaged the pharmaceutical for the benefit of, but not limited to, increasing shelf life of the compound and to increase the product visibility. One would have had a reasonable expectation for success in packaging the pharmaceutical in order to prolong the shelf life, as packaging pharmaceuticals is widely practiced in the formulary arts in order to generate sales.

Furthermore, it would have been obvious to have added into the composition and/or kit a protease inhibitor to prevent protein degradation/cleavage during storage to increase the shelf life. One would have been motivated to have added a protease inhibitor to the composition/kit because oxytocin and secretin are both peptide compounds, susceptible to proteolysis, and to increase the shelf life of the peptides in the composition. One would have had a reasonable expectation for success in making the composition/kit with a protease inhibitor as PIERCE teaches protease inhibitors are added to prevent proteolytic cleavage of peptides during storage and to increase the shelf life.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12

USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654